

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BERNARD S. ESROCK

Appeal No. 2000-1763
Application No. 09/227,037

ON BRIEF

Before FRANKFORT, NASE, and JENNIFER D. BAHR, Administrative Patent Judges.
BAHR, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-15, which are all of the claims pending in this application, which is an application for reissue of U.S. Patent No. 5,591,389, issued January 7, 1997 on Application No. 08/447,894, filed May 23, 1995 (hereinafter "the patent"). Claims 1-14 of the patent have been amended and a new claim 15 has been added in this reissue application.

BACKGROUND

The appellant's invention relates to a method of making a disposable tubular device. An understanding of the invention can be derived from a reading of exemplary claims 1, 7, 12 and 15, which appear in the appendix to the appellant's brief.

The following rejections are before us for review.

(1) Claims 1-15 stand rejected under 35 U.S.C. § 251 as being based upon new matter added to the patent for which the reissue is sought.

(2) Claims 1-15 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application for patent was filed, had possession of the claimed invention.

(3) Claims 1-15 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a first and second die, does not reasonably provide enablement for a single die or no die.

Reference is made to the brief (Paper No. 11) and the final rejection and answer (Paper Nos. 6 and 12) for the respective positions of the appellant and the examiner with regard to the merits of these rejections.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

Rejections (1) and (2)

At issue in this appeal is the fact that claims 1-14 of the patent, which required steps of extruding a first material through a first die to form a tube and moving the tube through a second die while extruding a second material through the second die have been broadened such that the first die is not expressly recited. In other words, claims 1-14 as amended in this reissue application require merely extruding a first material to form a tube and moving the tube through a die while extruding a second material through the die. Additionally, a new claim 15 has been added in the reissue application which is even broader than amended claims 1-14, in that it simply requires forming a first material into a tube and forming a second material into a tube-support structure.¹

The basis of rejections (1) and (2) is the same; i.e., that the claims are not supported by the appellant's original disclosure, thereby running afoul of the written description requirement

¹ The enlarged scope of the claims in this reissue application is not prohibited by the fourth paragraph of 35 U.S.C. § 251, as this reissue application was filed on January 7, 1999, within two years of the January 7, 1997 issue date of the patent.

of the first paragraph of 35 U.S.C. § 112 and the new matter prohibition of the first paragraph of 35 U.S.C. § 251.

As the court stated in In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983):

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. The content of the drawings may also be considered in determining compliance with the written description requirement. (citations omitted)

The examiner's position, in essence, is that the appellant's originally filed written disclosure only describes a process that requires first and second dies (answer, page 4). According to the examiner, the broadest description of the process (column 2, lines 14-19) requires both first and second dies. This description reads as follows:

Generally, a method of making a disposable tubular device in accordance with the present invention comprises extruding a first material through a first die to form the tube and moving the tube through a second die while extruding a second material through the second die to form the tube-support structure.

Further, the examiner asserts that the use of a first and second die is critical and that a person having ordinary skill in the art would have readily understood that such a feature could not be omitted (answer, pages 5-7). In support of this assertion, the examiner points to the above-mentioned disclosure in column 2, lines 14-19, as well as a more detailed description in column 5, lines 6-25, of the appellant's specification, which reads as follows:

A disposable tubular device of the present invention (e.g., the syringe tip 24) is preferably made by a dual-extrusion method. A first material is extruded through a first die to form an inner tube 36. This die is configured such that extrusion of the first material through the first die forms an elongate tube with elongate flutes. The flutes extend along substantially the entire length of the tube. The fluted tube is then passed longitudinally through a second die while a second material is extruded through the second die and around the inner tube. The extruded tubes are then cut to length to form the tip 24. The second die is configured so that the outer tube 38 (sleeve) so formed fits snugly over the inner tube 36. The sleeve 38 constitutes a tube-support structure for maintaining the general overall shape of the inner tube 36. The flutes 46 and a portion of an inner surface 50 of the sleeve 38 define a plurality of fluid passageways 52. The first and second materials are selected so that the outer tube of the tip 24 is stiffer than the inner tube at the typical operating temperatures of the syringe (e.g., temperatures in the range of 50° F. to 110° F.).

We have carefully reviewed the appellant's specification, paying special attention to the above-mentioned portions alluded to by the examiner, but we perceive therefrom no indication that extrusion of a first material through a first die to form the tube and movement of the tube through a second die while a second material is extruded through the second die to form the tube-support structure is critical to the invention. As we see it, the critical features of the invention are the steps of forming an inner tube of a first pliable, resilient material adapted to form a fluid-tight seal with a medical instrument and forming a tube-support structure (outer tube) having a stiffness and hardness greater than that of the inner tube so as to make a tubular structure capable of releasable and sealing connection to a medical instrument. As pointed out in column 3, lines 33-38, of the appellant's specification, the inner tube and outer tube preferably are held together by a close friction fit or, alternatively, may be bonded together by

heat or with a suitable adhesive. Additionally, in the embodiment of Figure 7, the inner and outer tubes may be radially spaced to form an annulus (air passageway) therebetween, with the inner tube retained within the outer tube by a bend (column 6, line 63, to column 7, line 12). While the appellant's specification does disclose one exemplary method of making a tubular device in accordance with the invention wherein a first and second die are used, this appears to us to be merely a preferred embodiment (perhaps included to satisfy the best mode requirement of the first paragraph of Section 112), as evidenced by the use of the term "preferably" (column 5, line 7). From our viewpoint, the appellant's specification would have conveyed to one of ordinary skill in the art a broad teaching of forming an inner soft, resilient tube and an outer tube of stiffer and harder material than that of the inner tube so as to form a double-walled tubular device.

In further support of the assertion that the use of a first and second die is critical, the examiner points to the appellant's remarks in the response (Paper No. 6) filed June 17, 1996 during the prosecution of the application for the patent (answer, pages 4 and 6). Of particular interest to the examiner are the appellant's remarks in the last five lines on page 7 and in the third full paragraph on page 9 of that response. After reviewing that response in its entirety and the prior art discussed therein, we cannot conclude, as the examiner has, that the appellant has relied upon the use of first and second dies to distinguish the claimed invention over the prior art. Turning first to the remarks on page 7 of that response, it is our opinion that the

appellant was distinguishing the claimed method from those of the prior art on the basis that the prior art disclosed methods of forming a tube by extruding two materials so as to bond them together to form a tube having only a single passageway, rather than a tubular structure with a first passageway defined by a tube and a second passageway defined by the tube and the tube-support structure. With regard to the independent claims of the patent, the appellant's arguments in the second paragraph on page 8 of that response assert a distinction over the Bulushek reference on the basis that Bulushek lacks a first material of a sufficiently pliable material to form a seal around the nipple of a medical instrument. The appellant's remarks on page 9 alluded to by the examiner are directed merely to a further distinction of dependent claim 4 of the patent (claim 30 of the application prior to re-numbering) regarding the use of a second die configured to produce a friction fit and thus do not alter our conclusion in any way.

In sum, nothing in the appellant's original disclosure or the prosecution history indicates or suggests that the use of first and second dies in forming the tube and tube-support structure was essential or critical to either the operation or patentability of the invention.² For the foregoing reasons, we are of the opinion that neither the omission of the recitation of one of the first and second dies from claims 1-14 nor the presentation of new claim 15 lacking reference to any dies at all constitutes new matter not supported by the appellant's original disclosure. Accordingly, we shall not sustain rejection (1) or rejection (2).

² In this respect, the case before us is analogous to In re Peters, 723 F.2d 891, 893-94, 221 USPQ 952, 953 (Fed. Cir. 1983).

Rejection (3)

Insofar as the enablement requirement is concerned, the dispositive issue is whether the appellant's disclosure, considering the level of ordinary skill in the art as of the date of the appellant's application, would have enabled a person of such skill to make and use the appellant's invention without undue experimentation. In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563-64 (CCPA 1982). In calling into question the enablement of the appellant's disclosure, the examiner has the initial burden of advancing acceptable reasoning inconsistent with enablement. Id. Moreover, we note that it is the function of the specification, not the claims, to set forth the "practical limits of operation" of an invention. One does not look to claims to find out how to practice the invention they define, but to the specification. See In re Johnson, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977).

In rejecting the claims, the examiner takes the position that the specification, while being enabling for a process using a first and second die, does not reasonably convey enablement for a single die or no dies (answer, page 3). At the outset, we note that, while claims 1-14 do not expressly require more than one die and claim 15 does not expressly require any die, none of the claims in this reissue application explicitly precludes the use of first and second dies. The claims recite a method of forming a tubular device adapted for releasable and sealing connection to a medical instrument having a nipple, the method including the steps of forming a first pliable material into a tube and forming a second harder material into a tube-support

structure. While the claims are not specific as to the procedure used in carrying out these forming steps, one need only look to the appellant's specification (column 5, lines 6-17) for at least one example of how to do so. Therefore, it is our opinion that the specification contains sufficient disclosure so as to enable one of ordinary skill in the art to practice the appellant's claimed invention.

Accordingly, we shall not sustain rejection (3).

REMAND TO THE EXAMINER

We remand this reissue application to the examiner for consideration of the patentability of the appellant's claims under 35 U.S.C. §§ 102 and 103 in light of the following comments with regard to the breadth of these claims.

We observe that the claims presented in this reissue application, and claim 15 in particular, are directed merely to forming a tubular device comprising a pliable elongate tube of a first resilient material and a tube-support structure of a second material having a stiffness and surface hardness greater than that of the tube, with a first passageway formed by the tube and a second passageway formed by the tube and tube-support structure. While each of the claims recites that the tubular device is adapted for releasable and sealing connection to a medical instrument having a nipple and the first material is sufficiently pliable to form a seal around the nipple, none of the claims requires a step of so connecting the tubular device to such a medical instrument.

Merely by way of example, U.S. Patent No. 5,167,623³, issued December 1, 1992 to Cianci et al., discloses a multi-lumen catheter (tubular device) comprising an outer tube 18 and an inner tube 20 made of a softer material than that of the outer tube 18 (abstract and column 3, lines 5-13). A lumen 24 is defined between the inner wall 26 of the outer tube 18 and the outer wall 28 of the inner tube 20 and extends throughout the entire length of the tube 18. Additional lumens 30, 32 are defined by the inner tube 20 (column 3, lines 14-24). While the Cianci patent does not disclose the details of forming the tubes 18 and 20 so as to form the multi-lumen catheter, other than to mention that the lumens 30, 32 may be formed by extrusion, the steps of forming the tube 20 from a first soft material and the tube 18 from a less soft second material (as broadly recited in claim 15) must inherently be included in the method of forming. While the inner tube 20 is not disclosed as forming a seal around a nipple for sealing against fluid leakage, the relatively soft inner tube 20 appears to us to be capable of forming such a seal around a nipple of appropriate size, material and surface characteristics. Thus, this application is remanded to the examiner for consideration, on the record, of the patentability of the appellant's claims (particularly claim 15) over the Cianci patent (either alone or in combination with other prior art references) or other prior art references.

³ This patent was cited by the appellant in Paper No. 4 during prosecution of the application for patent.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1-15 under 35 U.S.C. § 251 and under the first paragraph of 35 U.S.C. § 112 (both description and enablement requirements) is reversed. The application is remanded to the examiner for consideration of the above-mentioned issues.

REVERSED AND REMANDED

CHARLES E. FRANKFORT
Administrative Patent Judge

JEFFREY V. NASE
Administrative Patent Judge

JENNIFER D. BAHR
Administrative Patent Judge

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